

Smallpox Vaccine Working Group Introduction

Lee Harrison, MD
ACIP, Working Group Chair

June 24, 2015



Background

- Numerous occurrences of laboratory-acquired vaccinia infection have been reported
- Smallpox vaccine provides cross-protection against all orthopoxviruses (smallpox, monkeypox, vaccinia, and cowpox)
- Smallpox vaccine used to protect clinical and research laboratory workers against these viruses



Ocular vaccinia infection in laboratory worker treated with VIG and with full recovery



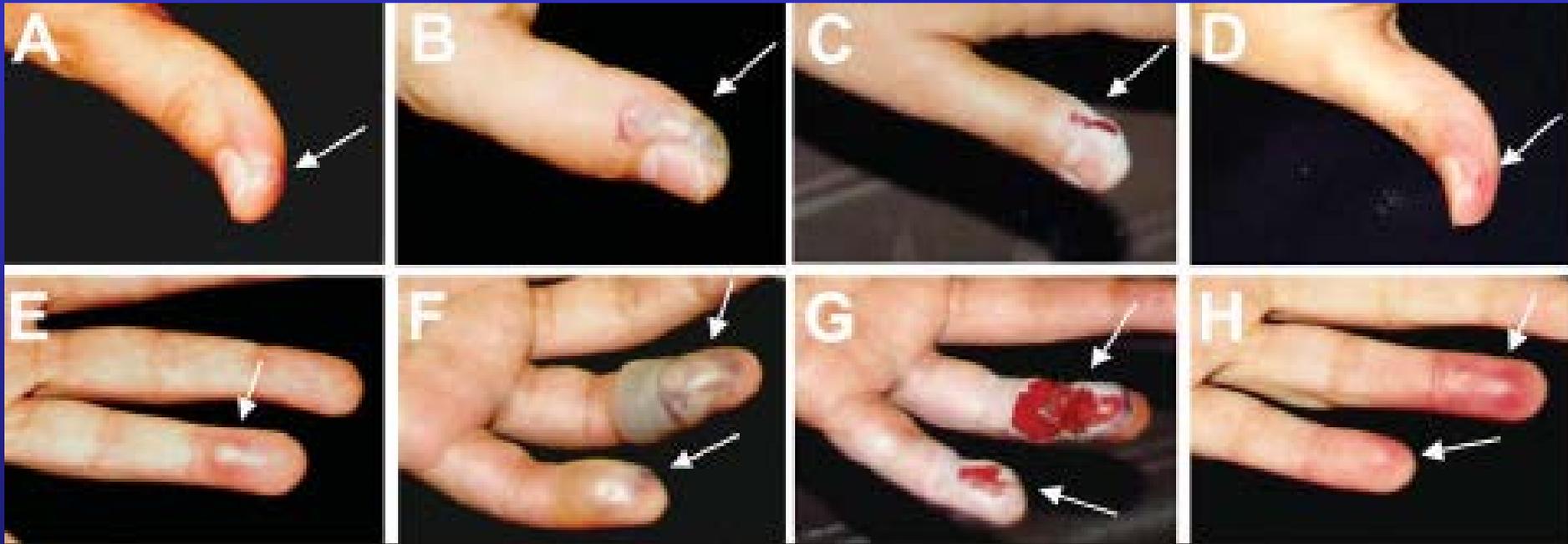
Primary lesion: Inner canthus



Satellite lesion: Lower conjunctiva

Lewis FMT et al. Emerg Infect Dis 2006;12:134

Needlestick inoculation of vaccinia virus in laboratory worker



Moussatché N et al. *Emerg Infect Dis* 2003;9:724



Left eye and right ear of man with laboratory-acquired vaccinia infection



Smallpox: Vaccination Complications



**Fatal progressive vaccinia/vaccinia necrosum
in child with immunodeficiency**

MMWR Dispatch 2003;52:1



Smallpox: Vaccination Complications



Progressive vaccinia in 62 yo woman with chronic lymphocytic leukemia

MMWR Dispatch 2003;52:1



Eczema vaccinatum in a 27 year old man with a history of atopic dermatitis



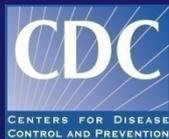
- Developed supraglottic edema, SOB
- Vaccinia immune globulin + supportive care
- Cultures of vesicular fluid: vaccinia virus
- Survived, with deep facial and chest scars

Risks of vaccination vs. laboratory infection

- Vaccination
 - Well formulated virus and dosage
 - Delivered through controlled route at location that minimizes risk of spread
- Laboratory infection
 - Strains with unknown pathogenic potential
 - High titers of virus
 - Delivered through unusual route: deep injection, atypical site on body, ocular exposure



Source: Mary Reynolds



Background

- ACIP recommendations for smallpox vaccination of laboratory workers not updated since 2003
- New smallpox vaccine, ACAM2000, licensed in 2007 and has replaced previously used smallpox vaccine, Dryvax



Background

- Smallpox Vaccine Working group established in March 2013
- Monthly meetings held since that time



Work Group Members

ACIP Members

Lee Harrison, Chair

Nana Bennett

Liaisons

Greg Poland (ACP)

Grace Kubin (APHL)

Howard Minkoff (ACOG)

May Chu (CLIAC)

FDA

Doran Fink

Sixun Yang

DOD

Limone Collins

Jay Montgomery

NIH

Mark Challberg

Richard Gorman

James Schmitt

Consultants / Content Experts

Stuart Isaacs (University of PA)

Mike Merchlinsky (BARDA)

Richard Greenberg (University of KY)

Richard Moyer (University of FL)

CDC

Brett Petersen (CDC Lead)

Mary Reynolds

Inger Damon

Shannon Keckler

Tiara Harms

Mike McNeil (ISO)

Maria Cano (ISO)

Jesse Geibe

Eric Sergienko

Alison Mawle



Terms of Reference

1. Review recommendations for smallpox vaccination for lab workers in 2001 statement (and supplements from 2003)
 - a. Review Biosafety in Microbiological and Biomedical Laboratories (BMBL) requirements for work with orthopoxviruses
 - b. Review orthopoxvirus laboratory exposure cases and reports



Terms of Reference

2. Review data on smallpox vaccine:
 - a. ACAM2000
 - Safety and immunogenicity data
 - Adverse event rates with current stringent prescreening program
 - b. Dryvax: Publications on 2002–2004 pre-event smallpox vaccination program

Terms of Reference

3. Review human safety and animal model efficacy data for attenuated smallpox vaccine IMVAMUNE stored in Strategic National Stockpile and potential role in smallpox vaccination for lab workers (unlicensed product and therefore informational)



Terms of Reference

4. Review data on recombinant vaccinia viruses in development or under investigation in clinical trials to provide guidance on need for smallpox vaccination in healthcare and/or laboratory personnel working with these viruses



Terms of Reference

5. Revise existing statement and supplements for smallpox vaccination of laboratory workers into single ACIP Policy Note document



Thank you

